

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively the “United States”); Medtronic, Inc. (Medtronic); and Kathy Onwezen, Elaine Bennett, Alan Brill, and Adolfo Schroeder (collectively the “Relators”), through their authorized representatives. Collectively, all of the above will be referred to as “the Parties.”

RECITALS

A. Medtronic is a Minnesota corporation headquartered in Fridley, Minnesota. At all relevant times herein, Medtronic developed, manufactured, distributed, marketed, and sold cardiac rhythm management devices in the United States, including pacemakers and implantable cardioverter defibrillators (“ICDs”).

B. On December 6, 2007, Kathy Onwezen and Elaine Bennett filed a *qui tam* action in the United States District Court for the District of Minnesota captioned *United States ex rel. Onwezen and Bennett v. Medtronic, Inc.*, Civ. No. 0:07-sc-04777, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b); and on April 18, 2008, an Amended Complaint was filed by Kathy Onwezen, Elaine Bennett, and Alan Brill captioned *United States ex rel. Onwezen, Bennett and Brill v. Medtronic, Inc.*, Civ. No. 0:07-sc-04777 (the “Minnesota Civil Action”). Relators Onwezen, Bennett and Brill allege, among other things, that Medtronic used post-market clinical studies and device registries as vehicles to pay participating physicians kickbacks to implant Medtronic pacemakers and ICDs in Medicare beneficiaries.

C. On January 23, 2009, Adolfo Schroeder filed a *qui tam* action in the United States District Court for the Eastern District of California captioned *United States ex rel. Schroeder v.*

Medtronic, Inc., Civ. No. [Redacted], pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “California Civil Action”). Relator Schroeder alleges, among other things, that Medtronic used post-market clinical studies and device registries as vehicles to pay participating physicians kickbacks to implant Medtronic pacemakers and ICDs in Medicaid beneficiaries.

D. Medtronic has entered or will be entering into separate settlement agreements, described in Paragraph 1(b) below (hereinafter referred to as the “Medicaid State Settlement Agreements”) with certain states and the District of Columbia in settlement of the Covered Conduct. States with which Medtronic executes a Medicaid State Settlement Agreement in the form to which Medtronic and the National Association of Medicaid Fraud Control Units (NAMFCU) Negotiating Team have agreed, or in a form otherwise agreed to by Medtronic and an individual State, shall be defined as “Medicaid Participating States.”

E. The United States contends that Medtronic submitted or caused to be submitted claims for payment to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and to the Medicaid Program (Medicaid), Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5.

F. In the course of Medtronic’s business, Medtronic conducted a post-market clinical study known as “FLOW” between February 1, 2004 and July 31, 2006; a post-market clinical study known as “TRENDS” between November 1, 2003 and February 28, 2006; a device registry known as “OMNI” between September 1, 2005 and August 31, 2011; and a device registry known as “P3” between March 1, 2004 and April 31, 2006 (collectively referred to herein as “the Subject Studies and Registries”).

G. The United States contends that it and the Medicaid Participating States have certain civil claims against Medtronic arising from the following conduct: Medtronic used the Subject Studies and Registries as vehicles to pay participating physicians kickbacks to implant Medtronic pacemakers and ICDs. Although Medtronic collected data and information from participating physicians, it knowingly and intentionally used the Subject Studies and Registries as a means of increasing device sales by paying certain targeted physicians to participate in the Subject Studies and Registries, which involved the use of select Medtronic pacemakers and ICDs. Each of the Subject Studies and Registries required a new or previous implant of a Medtronic device in each patient. In each case, Medtronic paid each participating physician a fee. The United States further contends that Medtronic, acting through its employees, solicited certain physicians for the Subject Studies and Registries in order to convert their business from a competitor's product and/or persuade the physicians to continue using Medtronic products.

As a result of the foregoing conduct, the United States alleges that Medtronic caused false or fraudulent claims for pacemakers and ICDs relating to the Subject Studies and Registries to be submitted to Medicare and Medicaid. That conduct is referred to below as the "Covered Conduct."

H. Medtronic denies the allegations in the Covered Conduct and expressly denies any wrongdoing or liability for the Covered Conduct. This Settlement Agreement is neither an admission of liability by Medtronic nor a concession by the United States that its claims are not well founded.

I. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Medtronic agrees to pay to the United States and the Medicaid Participating States, collectively, the sum of \$23,500,000, plus accrued interest at the rate of 2.875% per annum from April 27, 2011, and continuing until and including the day of payment (the "Settlement Amount"). The Settlement Amount shall be paid to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Medtronic shall pay to the United States the sum of \$22,655,200.00, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than the latter of seven (7) business days after the Effective Date of this Agreement or three (3) business days after receiving written instructions from the United States.

(b) Pursuant to the terms of a separate agreement entered into between Medtronic and the Medicaid Participating States, Medtronic shall pay to the Medicaid Participating States the maximum sum of \$844,800.00, plus accrued interest as set forth above ("Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall be paid by Medtronic to the New York State Attorney General's National Global Settlement Account as provided by the separate agreement.

2. Conditioned upon the United States receiving the Settlement Amount from Medtronic and as soon as feasible after receipt, the United States shall pay the total sum of

\$3,804,500.00, by electronic funds transfer, to Relators Onwezen, Bennett and Brill, pursuant to 31 U.S.C. § 3730(d), as the relator share of the federal proceeds of the Minnesota Civil Action. Conditioned upon the United States receiving the Settlement Amount from Medtronic and as soon as feasible after receipt, the United States shall pay the total sum of \$160,160.00, by electronic funds transfer, to Relator Schroeder as the relator share of the federal proceeds of the California Civil Action for the Covered Conduct as defined in this Agreement. No other relator payments shall be made by the United States with respect to the matters covered by this Agreement.

3. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Medtronic's full payment of the Settlement Amount, the United States releases Medtronic, together with its current and former parent corporations; current and former directors, officers, employees, and agents; direct and indirect subsidiaries; brother or sister corporations; divisions; and the successors and assigns of any of them, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 6 below, and conditioned upon Medtronic's full payment of the Settlement Amount, Relators, for themselves and for their heirs, successors, agents, and assigns, release Medtronic together with its predecessors, successors, subsidiaries, affiliates, and its present and former directors, officers, shareholders, members,

employees, administrators, partners, agents, attorneys and accountants (collectively “the Releasees”) from all of the following claims:

(a) Any and all federal claims, whether disclosed or undisclosed, which Relators have asserted, could have asserted, or may assert now or in the future against the Releasees related to the Civil Actions, the Covered Conduct, clinical studies and registries in general, and the Relators’ investigation and prosecution thereof, including but not limited to any civil monetary claim the Relators or the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; any claim for attorney’s fees, expenses or costs under 31 U.S.C. § 3730(d); and any claims with respect to any Relator’s employment with Medtronic, including but limited to any claim for retaliation under 31 U.S.C. § 3730(h) except for claims that Relator Schroeder has in the California Civil Action for conduct other than (1) the Covered Conduct and (2) conduct related to clinical studies and registries in general; and

(b) Any and all claims (including attorney’s fees, costs, and expense of every kind and however denominated), whether disclosed or undisclosed, which Relators have asserted, could assert, or might assert now or in the future against Releasees under federal or state law, regulation, rule or ordinance, and/or public policy, common law contract, or tort claim, including any claims arising out of or in any way connected with the Civil Actions, Covered Conduct, clinical studies and registries in general, and Relators’ employment or cessation of employment except for (1) claims that Relator Schroeder has in the California Civil Action for conduct other than (i) the Covered Conduct and (ii) conduct related to clinical studies and registries in general, and (2) any claims that Relator Schroeder may have pending in any separate actions brought under California state law prior to the Effective Date of this Agreement.

Relators represent that they know of no cause of action that they currently possess against Releasees other than the remaining claims that Relator Schroeder has in the California Civil Action and other than California state law claims that Relator Schroeder might have pending as of the Effective Date of this Agreement in a separate action.

5. OIG-HHS expressly reserves the right to institute, direct, or maintain any administrative action seeking exclusion against Medtronic, together with its current and former parent corporations; current and former directors, officers, employees, and agents; direct and indirect subsidiaries; brother or sister corporations; divisions; and the successors and assigns of any of them, from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), 42 U.S.C. § 1320a-7(b) (permissive exclusion), or 42 U.S.C. § 1320a-7a (permissive exclusion).

6. Notwithstanding the releases given in paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- (a) Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- (b) Any criminal liability;
- (c) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- (d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

- (e) Any liability based upon obligations created by this Agreement;
- (f) Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- (g) Any liability for failure to deliver goods or services due; or
- (h) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relators' receipt of the payments described in Paragraph 2, Relators and their heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its officers, agents, and employees, from any claims arising from the filing of the Minnesota Civil Action or the California Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Minnesota Civil Action or the California Civil Action, except for any claims that Relator Schroeder has to a share of the proceeds in the California Civil Action for all conduct other than the Covered Conduct as defined in this Agreement.

8. Medtronic waives and shall not assert any defenses Medtronic may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or

administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

9. Medtronic fully and finally releases the United States, and its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Medtronic has asserted, could have asserted, or may assert in the future against the United States, and its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. Medtronic, for itself and its predecessors, successors, subsidiaries, affiliates, present and former directors, officers, shareholders, members, employees, administrators, partners, agents, and accountants (collectively, "MDT"), releases and forever discharges the Relators and their heirs, successors, and assigns (collectively, the "Relator Releasees") from any and all claims, actions, causes of action, suits, debts due, payments, demands, rights, damages, losses, expenses, costs, fees, accounts, accountings, obligations, arbitrations, judgments, executions, injunctions, awards, rights of contribution, indemnification and apportionment, attorneys' fees and any and all other liabilities of any nature or amount, whether presently asserted or unasserted, accrued or unaccrued, which MDT ever had or now has against the Relator Releasees from any date up to and including the Effective Date of this Agreement, arising from or in any way relating to the Minnesota Civil Action, California Civil Action, Relators' allegations in those actions, or any Relator's prior relationship with MDT. Medtronic represents that it knows of no cause of action that it currently possesses against any Relator.

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or any state payer, related to the Covered Conduct; and Medtronic agrees not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct and agrees not to appeal any such denials of claims.

12. Medtronic agrees to the following:

(a) “Unallowable Costs” Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Medtronic, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States’ civil investigation(s) of the matters covered by this Agreement;
- (3) Medtronic’s investigation, defense, and corrective actions undertaken in response to the United States’ civil investigation(s) in connection with the matters covered by this Agreement (including attorney’s fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Medtronic makes to the United States pursuant to this Agreement and any payments that Medtronic may make to Relators, including costs and attorneys’ fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as “Unallowable Costs”).

(b) Future Treatment of Unallowable Costs: If applicable, Unallowable Costs shall be separately determined and accounted for by Medtronic, and Medtronic shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Medtronic or any of its subsidiaries or affiliates to Medicare, Medicaid, TRICARE, or FEHBP.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Medtronic further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including but not limited to payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Medtronic or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Medtronic agrees that the United States, at a minimum, shall be entitled to recoup from Medtronic any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its right to disagree with any calculations submitted by Medtronic or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Medtronic or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Medtronic's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 14 (waiver for beneficiaries paragraph), below.

14. Medtronic agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the claims defined as Covered Conduct.

15. Upon receipt of the payments described in Paragraph 1, above, the United States shall file a Notice of Intervention in Part and Declination in Part in the Minnesota Civil Action, as follows:

(a) The United States shall intervene in the Minnesota Civil Action as to the Covered Conduct only; and

(b) The United States shall decline as to all other allegations set forth in the Minnesota Civil Action.

16. Upon receipt of the payments described in Paragraph 1, above, the United States shall file a Notice of Intervention in Part in the California Civil Action as to the Covered Conduct only.

17. Upon receipt of the payments described in Paragraph 1, the United States and Relators Onwezen, Bennett and Brill shall promptly file a Joint Stipulation of Dismissal in the Minnesota Civil Action, as follows:

(a) The Joint Stipulation of Dismissal in the Minnesota Civil Action shall be with prejudice as to the United States' and Relators' claims as to the Covered Conduct and consistent with the terms and conditions of this Agreement; and

(b) The Joint Stipulation of Dismissal in the Minnesota Civil Action shall be without prejudice to the United States and with prejudice as to Relators as to all other claims.

18. Upon receipt of the payments described in Paragraph 1, the United States and Relator Adolfo Schroeder shall promptly file a Joint Stipulation of Partial Dismissal as to Medtronic in the California Civil Action, as follows:

(a) The Joint Stipulation of Partial Dismissal in the California Civil Action shall be with prejudice as to the United States as to the Covered Conduct and with prejudice as to the Relator as to the Covered Conduct and as to any conduct related to clinical studies and registries in general, all consistent with the terms and conditions of this Agreement;

(b) The following claims against Medtronic shall not be dismissed until they are settled, adjudicated, or otherwise resolved, and the Court before which the California Civil Action is pending is so informed: (1) all claims that Relator Schroeder has in the California Civil Action for all conduct other than the Covered Conduct and any conduct related to clinical studies

and registries in general; and (2) claims that Relator Schroeder has for any share under the Medicaid State Settlement Agreements.

19. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

20. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

21. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Minnesota. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

22. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

23. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

24. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

25. This Agreement is binding on Medtronic's successors, transferees, heirs, and assigns.

26. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

27. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

28. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Electronic copies of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 11/23/11

BY: 

COLIN M. HUNTLEY
ADAM J. SCHWARTZ
Trial Attorney
Commercial Litigation Branch, Civil Division
United States Department of Justice

DATED: 11/22/11

BY: 

CHAD A. BLUMENFIELD
Assistant U.S. Attorney
United States Attorney's Office
District of Minnesota

DATED: 11/22/11

BY: 

CATHERINE SWANN
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of California


DATED: 11/21/11

BY: 


GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

MEDTRONIC, INC.

DATED: 11/18/11

BY: 
D. CAMERON FINDLAY
Senior Vice President, General Counsel and Secretary
Medtronic, Inc.

DATED: 11/18/11

BY: 
STEPHEN J. UMMELT
COREY W. ROUSH
Hogan Lovells US LLP

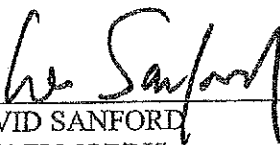
Counsel for Medtronic, Inc.

RELATOR KATHY ONWEZEN

DATED: 11/17/11

BY: 
KATHY ONWEZEN

DATED: 11/16/11

BY: 
DAVID SANFORD
GRANT MORRIS
Sanford Wittels and Heisler LLP

Counsel for Kathy Onwezen

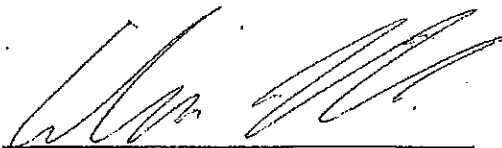
RELATOR ELAINE BENNETT

DATED: 11-21-11 BY: Elaine Bennett
ELAINE BENNETT

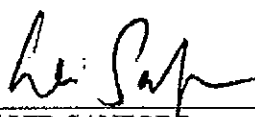
DATED: 11.22.11 BY: Mitch Kreindler
MITCH KREINDLER
Kreindler and Associates
Counsel for Elaine Bennett

RELATOR ALAN BRILL

DATED: 11/17/11

BY: 
ALAN BRILL

DATED: 11/16/11

BY: 
DAVID SANFORD
GRANT MORRIS
Sanford Wittels and Heisler LLP


Counsel for Alan Brill

RELATOR ADOLFO SCHROEDER

DATED: _____

BY: _____
ADOLFO SCHROEDER

DATED: 11/17/11

BY: 
C. BROOKS CUTTER, ESQ.
Kershaw Cutter & Ratinoff, LLP

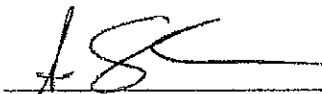
Counsel for Adolfo Schroeder

DATED: _____

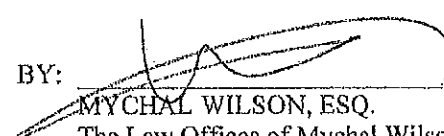
BY: _____
MYCHAL WILSON, ESQ.
The Law Offices of Mychal Wilson , LLP

Counsel for Adolfo Schroeder

RELATOR ADOLFO SCHROEDER

DATED: 11/07/11 BY: 
ADOLFO SCHROEDER

DATED: _____ BY: _____
C. BROOKS CUTTER, ESQ.
Kershaw Cutter & Ratnoff, LLP
Counsel for Adolfo Schroeder

DATED: 11/17/11 BY: 
MYCHAL WILSON, ESQ.
The Law Offices of Mychal Wilson, LLP
Counsel for Adolfo Schroeder